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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,437	12/17/2001	Stephen A. Johnston	5171-00041	2358

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EXAMINER
FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/023,437	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *92,94,95 and 104-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92, 94-95 and 104-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment, remarks and Exhibit 1 filed October 26, 2007 has been entered. Claims 1-91, 93 and 96-103 have been cancelled. Claims 92 and 94-95 have been amended. Claims 92, 94-95 and 104-121 are under examination.

New Grounds of Rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter. Independent 92 in particular, reads on a product that exists in nature because it recite "...administering a *Chlamydia psittaci* antigen...". This rejection may be obviated, if the claims are amended to an "isolated or purified" *Chlamydia psittaci* antigen.

Scope of Enablement

3. Claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of immunizing an animal comprising the step of administering a genetic vaccine comprising pooled DNA clones or full-length genes and/or fragments from *Chlamydia psittaci* (see Example 8 and Example 9) and a protein vaccine comprising a pool of full-length proteins and/or a pool of protein fragments from *Chlamydia psittaci* (see Example 9) in an amount effective to induce an immune response against *Chlamydia psittaci;* does not provide enablement for a method of immunizing an animal comprising the step of administering a single *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci;* wherein the *Chlamydia psittaci* antigen comprises the amino acid sequence as set forth as SEQ ID Nos. 7, 9, 11 and 13 (examined sequences).

The claimed invention is directed to a method of immunizing an animal comprising administering to the animal a single isolated *Chlamydia psittaci* antigen. The instant specification has not enabled the claimed invention. The specification has shown enablement for immunizing cattle with a pool of 14 DNA genes. See Example 8 and Table 4 of the instant specification. The specification has also shown enablement for a genetic vaccine comprising a pool of five protective full-length genes and/or gene fragments isolated in the gene screening process. The instant specification has further shown enablement for a protein vaccine which comprises full-length *Chlamydia psittaci* proteins and/or protein fragments. See Example 9 of the

specification. It should be noted that it is unclear as whether the genetic vaccine disclosed in Example 9 comprises a pool of full-length genes or gene fragments or a combination thereof. It is also unclear as to whether the protein vaccine disclosed in Example 9 comprises a pool of full-length proteins or protein fragments or a combination thereof. However, the genetic and protein vaccines disclosed in Example 9 appear to aid in fertility. It should be noted that the vaccine compositions used to vaccinate the animals in the specification comprise pools of genes or proteins. Thus, one of skill in the art cannot ascertain whether one single gene or protein or a combination of genes or proteins provide the protection described in Examples 8 and 9 of the instant specification. It is unclear as to *which specific genes* and *which specific proteins* are present in the vaccine compositions of Examples 8 and 9 of the instant specification. Further, if it's one single gene or protein that provided protection and fertility specifically, which single gene or protein is it?

As state above, the instant specification has only provided one example, Example 8, that relates specifically to vaccination of animals. However, this example immunizes the animals with a *pool of 14 gene clones*. Thus, the specification discloses a method of immunizing animals comprising a pooled DNA vaccine and *not a method of immunizing an animal comprising administering a Chlamydia psittaci protein vaccine comprising administering* ***one single*** *Chlamydia psittaci* antigen as recited in the instant claims. One of skill in the art would not reasonably conclude that a DNA vaccine and a protein vaccine would behave in the same manner when administered to an animal. It should be noted that the claimed method is directed immunizing an animal

with a single *Chlamydia psittaci* antigen in an amount that is effective in inducing an immune response to the administered *Chlamydia* antigen. Sato et al *(Science, Vol. 273, July 19, 1996, p.352-354)* teach that DNA vaccines do not necessarily induce immune response to the encoded antigen (see the Abstract).

Therefore, given the lack of success in the art, the lack of working examples commensurate in scope to the claimed invention and the unpredictability of the generation of a immune reaction to a specific antigen, the specification, as filed, does not provide enablement for a method of immunizing an animal comprising administering a *Chlamydia psittaci* protein vaccine comprising administering ***one single*** *Chlamydia psittaci* antigen.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification for a method of immunizing an animal comprising administering a *Chlamydia psittaci* protein vaccine comprising

administering one single *Chlamydia psittaci* in an amount effective to induce an immune response against *Chlamydia psittaci*, the amino acid sequence as set forth in SEQ ID NOs. 7, 9, 11 and 13) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use the claimed invention in a manner reasonable in correlation with the scope of the claims. Without proper guidance, experimentation is undue.

In view of all of the above, the unpredictably in the art, the lack of enablement and the lack of guidance in the instant specification, one of skill in the art would require guidance in order to make and use the claimed invention commensurate in scope with the claimed invention. Therefore, Applicant has failed to satisfy the requirements of 35 U.S.C. 112 first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 104-106 rejected under 35 U.S.C. 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 104 depends from independent claim 92. Claims 105 depends from claim 94 which depends from independent claim 92. Claim 106 depends from independent claim 92. Claims 104-106 recite "...wherein the step of preparing...". There is *not* a step of preparing in claim 92. Correction is required.

Status of Claims

5. No claims allowed.

6. The claimed invention appears to be free of the prior art.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VLF

Vanessa L. Ford
Biotechnology Patent Examiner
January 18, 2008

NITA MINNIFIELD
PRIMARY EXAMINER
1-22-08